UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/457,771	12/09/1999	R. MARTIN EMANUELE	19720-0624	8054

23594 7590 05/03/2002

JOHN S. PRATT
KILPATRICK STOCKTON LLP
1100 PEACHTREE
SUITE 2800
ATLANTA, GA 30309

EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	PAPER NUMBER
1635	18

DATE MAILED: 05/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/457,771	Applicant(s) EMANUELE ET AL.	
	Examiner Richard Schnizer	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-12 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-12 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/14/01 has been entered.

Claims 5 and 13 were canceled by Applicant in Paper No. 13, filed 5/24/01. Claims 1-4, 6-12, and 14-16 remain pending and under consideration in this Office Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6, 7, 9-12, 14, and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of U.S. Patent No. 5,811,088. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Instant claims 1-4, 6, 7, 9-12, 14, and 15 embrace compositions and methods for delivering oligonucleotides and antisense oligonucleotides to animals. The composition must comprise a nonionic block copolymer of polyoxypropylene (POP) and polyoxyethylene (POE). Instant claims 1-4 and 9-12 provide limitations as to the relative amounts of POE and POP in the composition. The narrowest claims in this regard are claims 4 and 12 which require that the copolymer is either CRL 8131 or CRL 8142. US Patent 5,811,088 teaches POE/POP copolymer compositions and methods for the delivery of "antisense and other modified oligonucleotides". See claim 26 at column 24. The specification of '088 teaches that especially preferred embodiments of the copolymers are the compounds designated CRL-8131 and CRL-8142. See column 11, lines 40-42 and 52-55. While the specification of an issued patent generally cannot be used as prior art to support a double patenting rejection, the courts have found that the portion of a patent disclosure which supports the patent claim may be considered when determining double patenting. "[T]his use of the disclosure is not in contrainvention of the cases forbidding its use as prior art, nor is it applying a patent as a reference under 35 USC 103, since only the disclosure of the invention claimed in the patent may be considered." See In re Vogel 422 F.2d 438, 441-42, 164 USPQ 619 (CCPA 1970), and MPEP 804 (II)(B)(1).

Instant claims 6 and 14 require a surfactant at 0.1-0.5% by weight, and a low molecular weight alcohol at 0.5-5-% by volume. These limitations are rendered obvious by the combination of claims 28 and 24 of '088, which recite these precise limitations. Pertinent to instant claims 7 and 15, '088 teaches that the surfactant may be Tween 80 (polyoxyethylene (20) sorbitan monooleate. See paragraph bridging columns 8 and 9.

Claims 1-4, 6, 7, 9-12, 14, and 15 are also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 5,674,911.

US Patent 5,674,911. teaches POE/POP copolymer compositions and methods for the delivery of "antisense and other modified oligonucleotides". See claim 3 at column 33. Pertinent to instant claims 1-4 and 9-12, '911 teaches that CRL 8131 and CRL 8142 may be used in the invention. See e.g. column 31, lines 23 and 24. Claim 5 of '911 discloses the limitations of instant claims 6 and 14. Pertinent to instant claims 7 and 15, '911 teaches that the surfactant may be Tween 80 (polyoxyethylene (20) sorbitan monooleate. See column 11, lines 39-46.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-12, and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6-12, and 14-16 are indefinite because they recite "human" and "animal" in the alternative. Humans are animals, thus they represent a species of the genus "animals" and cannot be represented as an alternative to animals.

Claims 1, 6-9, and 14-16 are indefinite because it is unclear what is the range of percentages of the copolymer which may be represented by polyoxyethylene because the claim is ungrammatical. The claims recite the following phrase in which the ungrammatical portion has been reproduced in bold print, "the molecular weight represented by the polyoxyethylene portion of the copolymer constitutes **between is approximately 1% and less than 50% of the polymer**. In the event that Applicant intended for the claim to read in part "constitutes between approximately 1% and less than 50% of the polymer", it is noted that this version would also be indefinite because one cannot know what is encompassed in the range of "1% to less than 50%". The upper limit of the range is unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 2 and 3 stand rejected under 35 U.S.C. 102(e) and 102(g) as being anticipated by Emanuele et al (US Patent 5,567,859, issued 10/22/96) for the reasons of record in Paper Nos. 10 and 14.

Emanuele teaches a composition comprising a block copolymer composed of POE and POP moieties, as well as either antibiotics, antisense oligonucleotides, triplex DNA compounds, or ribozymes. See column 1, lines 48-53; and column 2, lines 1-6. Preferred embodiments include a copolymer comprising a POP constituent of from 2250-4000 molecular weight, and about 10-30% (w/w) POE. See column 2, lines 55-62. The composition may also comprise 2% (w/w) Tween 80, and 1% (w/w) ethanol. See column 9, lines 2-4.

Thus Emanuele anticipates the claims.

The rejection under 35 USC 102(g) is made because, although the specification of Emanuele discloses the same invention as that disclosed in the instant application, the inventorship is not identical. Thus it is unclear who has invented the instant invention.

Response to Arguments

Applicant's arguments filed 5/30/01 have been fully considered but they are not persuasive.

Applicant argues that Emanuele et al ('859) is not prior art because the instant specification has been amended to claim priority to Application No. 08/138,271, filed 10/15/93. However, instant claims 2 and 3 require a POP portion of the copolymer with molecular weight between about 3250 and 15000 in combination with a POE portion which is "between approximately 5% and 25% of the copolymer." There is no literal support in the specification of 08/138, 271 for the combination of POP molecular weight from 3250-15000 and a POE portion of greater than 20%. For this reason, the priority date for claims 2 and 3 can be no earlier than 9/30/96, which is the filing date of 08/725,842.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to

the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.

JAMES KETTER
PRIMARY EXAMINER